

## REMARKS

### I. OVERVIEW

Applicants have reviewed and considered the Office Action dated December 14, 2005 and the references cited therewith. Claims 1 and 2 are pending in the instant application. Claim 1 has been amended. New claims 3-11 have been added. No new matter has been added. Support for the amendment and new claims can be found in the Published Specification at paragraphs 13, 31, and 51-52. Applicants respectfully request reconsideration of the above-identified application in view of the amendment and remarks that follow.

### II. PRIORITY

The Examiner writes that if applicant desires to claim the benefit of the prior-filed application under 35 U.S.C. § 120, a specific reference to the prior-filed application in compliance with 37 C.F.R. § 1.78(a) must be included in the first sentence of the specification following the title or in an application data sheet.

Applicants respectfully submit that the instant application properly claims benefit of priority under 35 U.S.C. §§ 120 to U.S. Application Serial Number 09/557,506 filed April 25, 2000. Therefore, Applicants are in compliance with 37 C.F.R. § 1.78(a).

### III. REJECTIONS UNDER 35 U.S.C. § 112

A. The Examiner writes that claims 1 and 2 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner writes that in claim 1, the word "modulator" in the claim renders the claim indefinite because the word "modulator" is

an indefinite term and neither the claim nor the specification sets forth what physical processes are intended to be encompassed in the scope of the term, thus the metes and bounds of the claim cannot be determined.

Applicants respectfully disagree. One skilled in the art reviewing the Specification, would understand the meaning of this term as used in the claims. The term "modulator" or variants thereof, for example, "modulating," as now recited in amended claim 1 is, as of Applicants' priority date, a recognized term of art. See Waldmann article (1999) cited by the Examiner. The Examiner is also referred to the instant Published Specification, at page 1, paragraph 2, lines 30-31, and page 1, paragraph 3, line 14. In this context, Applicants' have employed this term in a manner consistent with its generally accepted meaning. Thus, the term conveys the nature of the invention with clarity to the reader so that one reading the Specification would know that the term refers to compounds that activate or inhibit the ASIC channel in the presence or absence of FMRFamide or FMRFamide-related peptides. Therefore, the rejection should be withdrawn. In the event that the Examiner maintains the rejection, Applicants would welcome discussions with the Examiner regarding alternative acceptable terms that are synonymous with this term that is equally defined by the disclosure.

B. Claims 1 and 2 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Examiner writes that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner notes that the claims are directed to treating conditions by administering a therapeutically-effective amount of an antagonist, agonist, or modulator of

DEG/ENaC channel proteins, however no such therapeutically effective compounds are known to exist and nor does the specification describe them.

The Examiner writes that while it is certainly reasonable to expect the specific antagonists of specific DEG/ENaC channel proteins would some day be found and prove useful in the treatment of disorders such as pain and inflammation, as discussed by Waldmann-R et al., at the bottom of page 74, the instant specification provides no teaching of these yet to be found useful compounds. The Office Action states that due to a large quantity of experimentation necessary to find compounds that can be used in the claims and a lack of guidance in the specification regarding which structural features are required in order to provide activity undue experimentation would be required of the skilled artisan to make and use the claimed invention. Applicants respectfully disagree with the basis of the rejection as applied to amended claim 1 which now recites "comprising administering a composition that inhibits, activates or modulates the acid-sensing ion channels". Methods for identifying compounds which inhibit, activate or modulate the acid-sensing ion channels were known in the art as of Applicants' priority date as recognized by the Examiner. Office Action, at the bottom of page 4. In addition, Applicants have described a method for identifying compounds that activate or inhibit the ASIC channel in the presence or absence of FMRFamide or FMRFamide-related peptides. Published Specification, at page 6, paragraph 51. Given the state of art as of Applicants' priority date regarding the inhibition, activation or modulation of ASIC, it is submitted that it is appropriate to omit such disclosure from the instant patent application. MPEP §2164.01 provides that "A patent need not teach, and preferably omits, what is well known in the art."

Applicants submit that under both the holding and recited Wands factors, In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988), the pending claims are fully enabled. In Hybritech Inc. v.

Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81 (Fed. Cir. 1986), the Federal Circuit found that the claims were properly enabled even where one of ordinary skill in the art would have to engage in production and screening of numerous monoclonal antibodies to practice the invention. Similarly, one skilled in the art could determine whether a compound inhibits or activates an acid-sensing ion channel of the DEG/ENaC channel family and the amount necessary to treat conditions associated with the response of acid-sensing ion channels of the DEG/ENaC channel family.

Just as the Hybritech court recognized that the method for screening monoclonal antibodies was well known prior to Applicants' filing date, the methods for screening for inhibition, activation or modulation of the ASIC channel were well known prior to Applicants' filing date. See the Waldmann article, dated 1999. Accordingly, withdrawal of the rejection is respectfully requested.

#### IV. CONCLUSION

Please consider this a one-month extension of time from March 14, 2006 to April 14, 2006 and charge Deposit Account No. 26-0084 the amount of \$60.00 for the extension. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



JANAÉ E. LEHMAN BELL, Ph.D., Reg. No. 55,370  
McKEE, VOORHEES & SEASE, P.L.C.

801 Grand Avenue, Suite 3200

Des Moines, Iowa 50309-2721

Phone No: (515) 288-3667

Fax No: (515) 288-1338

**CUSTOMER NO: 22885**

Attorneys of Record

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